

REMARKS

In the Official Action dated April 8, 2009, Claims 1, 2, 4, 5, 7, 9-11, 13, 17 and 18 are pending. This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claims 1, 2, 4, 5, 7, 9-11, 13, 17 and 18 stand objected to for certain minor informalities.

Claims 1, 2, 4, 5, 7, 9-11 and 13 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent 6,468,526 to Chrisope et al. (hereinafter, "Chrisope") as evidenced by *Probiotics and prebiotics: Can regulating the activities of intestinal bacteria benefit health?* BMJ 1999: 318:999-1003 by MacFarlane et al. (hereinafter, "MacFarlane") in view of U.S. Patent 7,220,18 to Hans et al. (hereinafter, "Hans") and further in view of *Journal of Systematic Bacteriology*, 217-221, 1999 by Falsen et al. (hereinafter, "Falsen").

Claims 17 and 18 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Chrisope in view of Hans and Falsen as applied to Claims 1, 2, 4, 5, 7, 9-11 and 13 and further in view of MacFarlane.

Claims 2, 5, 7, 11, 17 and 18 have been amended to correct a minor informality.

Claims 1, 9 and 13 have been amended to recite administration of a second probiotic organism. Support for this amendment can be found in previously presented Claims 4 and 10, and throughout the application, specifically page 11 line 3-13.

Claims 4 and 10 have been canceled

Claims 5, 7 and 11 have been amended to change their dependencies.

No new matter is added by way of these amendments.

Applicants respectfully submit new claims 21-26 for examination. Claim 21 is directed to, *inter alia*, *Lactobacillus iners* being *Lactobacillus iners* Y16329. Claim 22 is directed to, *inter alia*, *Lactobacillus iners* being *Lactobacillus iners* CCP-1. Claim 23 is directed to, *inter alia*, *Lactobacillus iners* being *Lactobacillus iners* Y16329. Claim 24 is directed to, *inter alia*, *Lactobacillus iners* being *Lactobacillus iners* CCP-1. Claim 25 is directed to, *inter alia*, *Lactobacillus iners* being *Lactobacillus iners* Y16329. Claim 26 is directed to, *inter alia*, *Lactobacillus iners* being *Lactobacillus iners* CCP-1. No new matter has been added by way of the aforementioned Claim additions. For example, Applicant directs the Examiner's attention to page 16 lines 1-11. Applicant submits that the identified sections are presented only for the Examiner's convenience and is not intended to be an exhaustive list of support.

In view of the following remarks, Applicants request further examination and reconsideration of the present patent application.

Claim Objections

Claims 1, 2, 4, 5, 7, 9-11, 13, 17 and 18 stand objected to for informalities. Claims 2, 5, 7, 11, 17 and 18 have been amended to correct the minor informality. Thus the objections to the claims are overcome. Withdrawal of the objection and issuance of Claims 1, 2, 5, 7, 9, 11, 13, 17 and 18 is earnestly solicited.

Rejections Under 35 U.S.C. §103

Claims 1, 2, 4, 5, 7, 9-11 and 13 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Chrisope as evidenced by MacFarlane in view of Hans and further in view of Falsen.

This combination of references does not render the claimed invention obvious.

Chrisope teaches a bacterium of the genus *Lactobacillus* with desirable characteristics suitable for use in a vaginal medicament. See column 2 lines 50-52 of Chrisope. Chrisope further teaches that the *crispatus* and *jensenii* strains of *Lactobacillus* are superior to other strains for use in a vaginal medicament. See column 7 lines 39-42 of Chrisope. Chrisope also teaches application of a clindamycin cream followed by *Lactobacillus* suppositories containing the *Lactobacillus crispatus* CTV-05 strain to treat women with recurrent bacterial vaginosis (BV). See column 31 lines 28 to 33 of Chrisope. Clindamycin is a protein synthesis inhibitor lincosamide antibiotic, not, as stated on page 5 of the Official Action, a probiotic. Chrisope does not teach or suggest treatment of BV or methods of establishing healthy bacterial flora through a treatment of a first probiotic, *Lactobacillus iners*, and a second probiotic, as presently recited in Claims 1, 9, 13 and all claims depending therefrom of the present application. Further, Chrisope does not teach the use of *Lactobacillus iners*, as correctly stated on page 6 of the Official Action.

The Official Action states that Falsen teaches *Lactobacillus iners*. Falsen teaches identification of several strains of *Lactobacillus* isolated from human sources. See lines 1-5 right hand column page 218 of Falsen. Falsen, dated 1999, teaches the discovery of an unknown rod, which is phylogenetically quite distinct from several other *Lactobacillus* strains, including *crispatus* and *jensenii*. See left hand column and lines 1-3 right hand column page 220 of Falsen. Falsen further teaches the *iners* strain was until their discovery, an unrecognized species which is readily distinguishable from all other currently known lactobacilli. See lines 3-10 right hand column page 220 of Falsen. Falsen does state that Lactobacilli are important commercially, based on the growing interest in their use as probiotics, but Falsen does not teach a method or treatment involving *Lactobacillus* or the specific strain *iners*. See lines 8-12 left hand column page 217 of Falsen. More specifically, Falsen does not teach or suggest treatment or methods of

establishing healthy bacterial flora through a treatment of a first probiotic, *Lactobacillus iners*, and a second probiotic, as recited in Claims 1, 9, 13 and all claims depending therefrom of the present application.

MacFarlane teaches commercial preparations of lactobacilli. See right column page 999 of MacFarlane. MacFarlane does not teach specific strains of Lactobacilli, including *iners*, further, MacFarlane does not teach or suggest treatment or methods of establishing healthy bacterial flora through a treatment of a first probiotic, *Lactobacillus iners*, and a second probiotic, as recited in Claims 1, 9, 13 and all claims depending therefrom of the present application.

Hans teaches the secretion *in vivo* of trefoil peptides by microorganisms for treatment of inflammatory disorders of the gastro-intestinal tract, including the use of *Lactobacillus iners* as the microorganism to deliver the peptide. See column 1 lines 12-19 and column 2 line 49 to column 3 line 52 of Hans. Hans does not teach or suggest treatment or methods of establishing healthy bacterial flora through a treatment of a first probiotic, *Lactobacillus iners*, and a second probiotic, as recited in Claims 1, 9, 13 and all claims depending therefrom of the present application.

It would not have been obvious to one of ordinary skill in the art to substitute the *Lactobacillus* strain *iners* as described in Falsen with the strains described in Chrisope. This substitution would not have been obvious, because not only did the inventors of Chrisope not know of or consider the effects and use of this other strain in their disclosure, the *iners* strain was discovered 1 year after the original filing in the Chrisope case. Further, the strain *iners* is phylogenetically quite distinct, and has several different reactions to mediums of growth as taught by Falsen.

Further, no reference teaches or suggests treatment or methods of establishing healthy bacterial flora through a treatment of a first probiotic, *Lactobacillus iners*, and a second probiotic, as recited in Claims 1, 9, 13 and all claims depending therefrom of the present application. Therefore the combination of Chrisope, MacFarlane, Hans and Falsen do not teach or suggest treatment or methods of establishing healthy bacterial flora through a treatment of a first probiotic, *Lactobacillus iners*, and a second probiotic, as recited in Claims 1, 9, 13 and all claims depending therefrom of the present application.

The rejection of 1, 2, 4, 5, 7, 9-11 and 13 under 35 U.S.C. §103(a) is therefore overcome. Withdrawal of the rejection and issuance of Claims 1, 2, 4, 5, 7, 9-11 and 13 is earnestly solicited.

Claims 17 and 18 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Chrisope in view of Hans and Falsen as applied to Claims 1, 2, 4, 5, 7, 9-11 and 13 and further in view of MacFarlane.

Claims 17 and 18, which depend on Claim 7, are not rendered obvious by the combination of Chrisope, Hans, Falsen and MacFarlane because the combination of references do not teach or suggest treatment or methods of establishing healthy bacterial flora through a treatment of a first probiotic, *Lactobacillus iners*, and a second probiotic, as recited in Claims 1, 7 and all claims depending therefrom of the present application. Further, the combination of references do not teach or suggest a prebiotic being inulin or fructo-oligosaccharides or milk.

New Claims 21-26 are patentable over the combination of Chrisope, MacFarlane, Hans and Falsen for at least the reason that the combination of references do not teach or suggest treatment or methods of establishing healthy bacterial flora through a treatment of a first probiotic, *Lactobacillus iners*, and a second probiotic, as recited in Claims 1, 9, 13 and all claims

depending therefrom of the present application. Further, the combination of references do not teach or suggest the specific *Lactobacillus iners* strains Y16329 and CCP-1.

It is respectfully submitted that the foregoing amendments and remarks effectively address each of the issues underlying the Examiner's rejections. Withdrawal of all outstanding objections and rejections is respectfully requested. It is therefore respectfully suggested that the claims are in condition for allowance, and that allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'Peter I. Bernstein', with a long horizontal flourish extending to the right.

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